

REMARKS / ARGUMENTS

In response to the Office Action of August 8, 2006, Applicants have amended claims 1 and 17 to recite "wherein said carrier composition is devoid of a hydrophilic phase" which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

Claims 11-20 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. On page 3 of the office action, the Examiner has asserted that: "there is no description in the specification for compositions that contain therapeutic agents and the carrier compositions now recited in claims 11 and 17." In response to the rejection, Applicants direct the Examiner to page 2, lines 14-27, which recitation is almost identical to presently amended claim 11. Element a) set forth on page 2, lines 14 –17 of the present specification, recites a Markush group consisting of polyglycerol fatty acid esters and sorbitan fatty acid esters. Presently amended claim 1 recites one of the members of the Markush Group, a sorbitan fatty acid ester. Elements b) and c) as well as "further optional pharmaceutically acceptable excipients" of claim 11 may be found on page 2, lines 19-27. Thus, it is respectfully submitted that the specification specifically describes the composition that contains the therapeutic agent and the carrier composition presently recited in claim 11.

Applicants further direct the Examiner to page 2, lines 14-17, and page 6, penultimate line to page 7, line 2, which specifically teach part a) of claim 17. Part b) of claim 17 is identical to part b) of claim 1 and is therefore specifically taught on page 2, lines 19-21 of the specification. Part c) of claim 17 is taught at page 2, lines 23-25, and

page 8, lines 19-21. It is respectfully submitted therefore, that the specification specifically describes the composition that contains the therapeutic agent and the carrier composition presently recited in claim 17.

In view of the amendments to claims 11 and 17 and the foregoing remarks, withdrawal of the rejection of claims 11-20 under the written description provision of 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 11-20 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Hauer et al. (U.S. Patent No. 5,342,625). Applicants respectfully traverse the rejection for the reasons set forth below. The teaching provided by Hauer et al. is limited to a pharmaceutical composition having as active ingredient cyclosporin as well as:

- 1) a hydrophilic phase;
- 2) a lipophilic phase; and
- 3) a surfactant.

"The cyclosporin is carried in the lipophilic phase. Suitably both the hydrophilic and lipophilic phases will serve as carrier medium." See Hauer et al., column 6, lines 35-53.

In contrast, presently amended claim 11 (and claims 12-16 depending therefrom) as well as presently amended claim 17 (and claims 18-20 depending therefrom), recite in relevant part, carrier compositions consisting essentially of (a) a sorbitan fatty acid ester co-surfactant; (b) a pharmaceutically acceptable oil which is essentially pure or which is in the form of a mixture, comprising a triglyceride as essential lipophilic component and (c) a non-ionic surfactant, wherein said carrier composition is devoid of a hydrophilic phase. Thus, in contrast to the compositions taught by Hauer et al., the carrier of the presently amended claims is *devoid of a hydrophilic component*.

On page 4 of the Office Action, the Examiner has referred to column 9, lines 40-47; Examples 1.6-1.10; and column 12, lines 35-41, of Hauer et al., in its disclosure of a

composition that comprises cyclosporine, oil, hydrophilic surfactant that has an HLB of less than 10 and excess surfactants which may be additional carriers and co-solvents as part of the hydrophilic or lipophilic phase (column 12, 42-48). The position of the Examiner is that sorbitan esters are equally useful as lipophilic surfactants while readily admitting that the specific combination of surfactants presently claimed is not disclosed by Hauer et al. According to the Examiner, polyglycerol esters are recognized in the art as lipophilic surfactants and directs Applicants to column 2, lines 2 –9 of Reggio et al., U.S. Patent No. 4,379,169 as a teaching reference.

In response, Applicants direct the Examiner to Column 8, lines 56-63, of Hauer et al., which provide: "Suitable components for use as lipophilic phase include any pharmaceutical acceptable solvent which is non-miscible with the selected hydrophilic phase, e.g., as defined under (1.1) or (1.2). *Such solvents will appropriately be devoid or substantially devoid of surfactant function.*" Since Hauer et al. specifically teach that the lipophilic phase of their composition is devoid or substantially devoid of surfactant function, it is submitted that any excess surfactant of Hauer et al. can only function as surfactant and replace some *but not all of the hydrophilic phase*. The hydrophilic phase of Hauer et al. however, is not met by either of Applicants' a) co-surfactant or c) surfactant components.

Applicants further respectfully submit that the Examiner has yet to provide a motivation or suggestion for Applicants' presently claimed pharmaceutical composition comprising a solubilized therapeutic agent which is sparingly soluble in water and a carrier composition, the carrier composition consisting essentially of:

a) about 10-50% by weight, based on the carrier composition, of a sorbitan fatty acid ester co-surfactant which is substantially pure or which is in the form of a mixture, having a hydrophilic-lipophilic balance of less than 10 (HLB value according to Griffin);

b) about 5-40% by weight, based on the carrier composition, of a pharmaceutically acceptable oil which is substantially pure or which is in the form of a mixture, comprising a triglyceride as essential lipophilic component; and

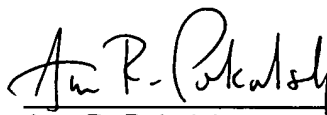
c) about 10-50% by weight, based on the carrier composition, of a nonionic surfactant which is substantially pure or which is in the form of a mixture, having an HLB value of more than 10; and further optional pharmaceutically acceptable excipients, *in the absence of any hydrophilic phase.*

As submitted previously by Applicants, Hauer et al. merely provides a "shotgun" disclosure listing multiple components to make up the surfactants, hydrophilic and lipophilic components. There is nothing in Hauer et al. to suggest to one skilled in the art the specific combinations of co-surfactant, lipophilic component and surfactant in the relative amounts and HLB values presently claimed. Nor does Hauer et al. provide any motivation to make such compositions. Accordingly, it is respectfully submitted that Hauer et al. fails to render obvious the subject matter of claims 11-20. Withdrawal of the rejection of claims 11-20 under 35 U.S.C. §103(a) is therefore warranted.

In view of the foregoing remarks and amendments, it is respectfully submitted that the pending claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted

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